

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of Spirituality Education Program on Depression and Anxiety in Patients with Multiple Sclerosis

#### Protocol summary

##### Study aim

Assess the effect of spirituality educational program on the anxiety and depression in patients with multiple sclerosis

##### Design

This study is a randomized controlled trial that is designed before and after with control group. Sixty eligible patients will be recruited to the study. They will be randomly allocated to an experimental and a control group using a table of random numbers

##### Settings and conduct

In the experimental group, patients will receive spirituality educations in eight ninety-minute weekly sessions in the Multiple Sclerosis Association, and in the control group, participants will receive routine illness education. anxiety and depression will be assessed one month after intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: definite diagnosis of multiple sclerosis(MS) for at least one year; having educational level of guidance school or higher; Having the minimum age of 20 and maximum of 50; Obtain score 16 to 28 from Beck Depression Inventory and 12-26 from Beck Anxiety Inventory; Exclusion criteria: having a history of psychotic disorders, dementia, and delirium; having history of using psychiatric medications in the past month; drug addiction; taking psychological therapies

##### Intervention groups

In the experimental group, patients will receive spirituality education in eight ninety-minute weekly sessions in the multiple sclerosis association, and in the control group, participants will receive routine education

##### Main outcome variables

Depression and Anxiety

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170404033212N2**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

#### Registration date

2018-02-16, 1396/11/27

#### Registrant information

##### Name

Siamak Amiri

##### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3433 4829

##### Email address

amiri.s@abzums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Alborz University of Medical Sciences

#### Expected recruitment start date

2018-02-01, 1396/11/12

#### Expected recruitment end date

2018-05-01, 1397/02/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Spirituality Education Program on Depression

and Anxiety in Patients with Multiple Sclerosis

**Public title**

Effect of Spirituality Education Program on Depression and Anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Definite diagnosis of Multiple Sclerosis based on Patients' Medical Records Having at least one year of history of suffering from multiple sclerosis Having educational level of guidance school or higher Having a minimum age of 20 and maximum of 50 Obtain score 16 to 28 from Beck Depression Inventory (mild to moderate depression) Obtain 12-26 Beck Anxiety Inventory (mild to moderate anxiety)

**Exclusion criteria:**

History of Psychotic Disorders, Dementia, or Delirium (based on their medical records) Taking psychiatric drugs (Anti-anxiety, Antidepressant, mood stabilizer) in the past month Having psychological therapies Drug Addiction (based on medical records and patients' self-reports)

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Table of random numbers

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Alborz University of Medical Sciences,

**Street address**

North Taleghani st., shahrak edari

**City**

Karaj

**Province**

Alborz

**Postal code**

3193914714

**Approval date**

2015-08-26, 1394/06/04

**Ethics committee reference number**

abzums.rec.1394.39

**Health conditions studied****1****Description of health condition studied**

Multiple Sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis

**Primary outcomes****1****Description**

Depression score in the Beck Depression Inventory

**Timepoint**

before and after 30 days

**Method of measurement**

Beck Depression Inventory

**2****Description**

Anxiety score in the Beck Anxiety Inventory

**Timepoint**

Before and After 30 days

**Method of measurement**

Beck Anxiety Inventory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the experimental group, patients will receive spirituality education in eight ninety-minute weekly sessions

**Category**

Prevention

**2****Description**

Patients in the control group will receive routine multiple sclerosis-related educations

**Category**

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alborz MS Association

**Full name of responsible person**

Shahrokh Abadian

**Street address**

Azadegan sq , Karaj

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+98 26 3256 7670

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohammad Noori Sepehr

**Street address**

North Taleghani, Shahrak Edari

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3146883411

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**Email**

abzums.research@gmail.com

**Web page address**

<http://www.abzums.ac.ir>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Karaj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Siamak Amiri

**Position**

Faculty member instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable